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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/924,428	08/07/2001	Lei Wu	4718420005000	3614
25225 7590 09/24/2007 MORRISON & FOERSTER LLP 12531 HIGH BLUFF DRIVE SUITE 100 SAN DIEGO, CA 92130-2040			EXAMINER CHEU, CHANGHWA J	
			ART UNIT 1641	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/924,428

Applicant(s)

WU ET AL.

Examiner

Jacob Cheu

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-20, 25-31, 33-93 and 95-125 is/are pending in the application.
- 4a) Of the above claim(s) 35-55, 58-66, 69-91 and 96-114 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13, 16-20, 25-31, 33, 34, 56, 57, 67, 68, 92, 93, 95, 115-122 and 125 is/are rejected.
- 7) ☒ Claim(s) 14, 123 and 124 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/19/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of Claims

Applicant's amendment filed on 7/19/2007 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 122-125 are added to the instant application.
2. Claims 35-55, 58-66, 69-91 and 96-114 are withdrawn from further consideration.
3. Currently claims 1-14, 16-20, 25-31, 33, 34, 56, 57, 67, 68, 92, 93, 95 and 115-125 are under examination.

Claim Rejections - 35 USC § 112

New Matter

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 122 and 125 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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It is noted that the features in newly added claims 122 , “wherein the magnetic material is a patterned magnetic material” and “wherein the patterned magnetic material is an encoding feature” in claim 125 do not have support from the specification.

Applicant is invited to clarify this matter in pointing out specific portion from the specification.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-13, 16-20, 25-31, 34, 67-68, 92-93, 95, 115-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaye et al. in view of Wu et al. (US 6221677).

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Kaye et al. teach a microdevice for combinational library screening. Kaye et al. teach that the microdevice comprises a substrate, a photorecognizing coding pattern on said substrate, and a binding partner for binding target molecule of interest (See page 6, line 5-15; page 2, line 1-5; Figure 2 and 5). It is noted that the photorecognizable code taught by Kaye et al. consists of different shapes and forms, including hollows, grooves, or notches, which are holes not penetrating through the entire depth of the substrate (See page 6, line 5-15; Figure 2 and 5; *Particular Figure 2, second example, holes not penetrated through the substrate*)(emphasis added). With respect to the dimensions, the microdevice taught by Kaye et al. can be within from 1 to 500 microns ranges (See page 9, last paragraph). The microdevice of Kaye et al. does not comprise an anodized metal surface layer (See page 10-15; Figure 2-5;). Kaye et al. also teach using the microdevice to test the ability of library elements or compounds, e.g. peptides, or peptoids, to modulate activity in biological systems, including cells, enzymes, receptors (See page 19, line 1-5). The microdevice can be conjugated with *beads* where the interest of target is immobilized thereon for screening (See page 19, line 12-20; Figure 7, particular Figure 7b)(emphasis added). However, Kaye et al. do not disclose the features of having a binding partner, e.g. antibody, capable of binding to a moiety to be manipulated and with magnetic material thereon.

Wu et al. teach immobilizing binding partner capable of being manipulated on the beads having magnetic materials (See Figure 4). The binding of the analyte can be separated or isolated by magnetic force. Supra.

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Kaye et al. with the binding partner, such as antibody, immobilized on a magnetic beads as taught by Wu et al. in order to improve efficiency of separation or isolation of the modulated target molecules.

With respect to claim 2, Kaye et al. teach that the material for microdevice can be of glass, rubber (See page 5, line 24-26).

With respect to claim 3, 11, Kaye et al. also teach use of silicon dioxide or a metal layer for the substrate (See Abstract).

With respect to claim 12, Kaye et al teach use of aluminum for the microdevice (page 11, line 19-21).

With respect to claim 4, the microdevice taught by Kaye et al is hydrophilic or hydrophobic (See Figure 2-5; page 2-3).

With respect to claims 5, 116, the shape of the microdevice can be different, such as rectangle or square (See Figure 2).

With respect to claims 6, 117-119, Kaye et al. teach that the thickness of the substrate can be the range between 5-50 microns (See page 9, line 21-25; page 21, line 17-21).

With respect to claims 7-10, Kaye et al. teach that the shape of the microdevice can be varied, and the size can be from 1 to 500 microns (See page 9, line 22-25).

With respect to claims 13, 28-31, Wu et al. also teach using electromagnetic materials for facilitation of the binding by physical force, such as magnetic interaction (See page 15, line 15-17).

With respect to claims 17-19, Kaye et al. teach the photorecognizable code on the microdevice can be of a plurality of holes on the substrate (See Figure 2; page 6, line 9-10).

With respect to claims 19-20, Kaye et al. teach lithographical micromachining for manufacturing the microdevice (See page 12, line 13-15; page 11, line 12-13).

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With respect to claims 25-27, the antibodies taught by Wu et al. can be manipulated, e.g. binding to the analyte. Surpa.

With respect to claim 34, Kaye teach using fluorescent or phosphorescent materials substance for detection purpose (See page 15, line 20).

With respect to claims 56-57, Kaye et al. teach that the microdevice can be manipulated on different layer(s) through micromachining or photolithographic (See page 12-13).

With respect to claim 93, the microdevice comprises a metal layer and a non-metal layer (See Abstract; page 10-12).

With respect to claim 115, the microdevice taught by Kaye et al. does not comprise a microprocessor (See Figure 2).

6. Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaye et al. in view of Wu, and further in view of Cattell (US 6180351).

Both Kaye and Wu et al. references have been discussed but are silent in teaching use of a detectable marker, such as fluorescent label for detection purpose.

Cattell et al. teach an addressable array, such as DNA detection. Cattell et al. teach use of fluorescent makers for increase detection efficiency (Col. 1, line 22-25). Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided Kaye and Wu et al. with the fluorescent maker as taught by Cattell et al. to increase detection sensitivity since it is well known in the art to use fluorescent label marker for detection purpose.

7. Claims 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaye et al. in view of Wu, and further in view of Zhou et al.

Both Kaye and Wu et al. references have been discussed but are silent in teaching use of chips for analysis.

Zhou et al. teach a biochip to detect manipulation of micro-particles and biological materials for economy and time-saving purposes (Col. 2, line 55-65).

Therefore, it would have been obvious to one ordinary skill in the art at the time the invention was made to have provided both Kaye and Wu et al. with the chip taught by Zhou et al. in order for a time-saving and cost-saving microanalysis.

Response to Applicant's Arguments

Applicant argues that "Kaye et al. reference makes absolutely no mention of a "microdevice". The passage merely describes a Combinatorial Library, which may be synthesized with devices that Kaye disclose" (See Remarks, page 20, last paragraph).

Applicant arguments have been considered, but are not persuasive.

Although the term "microdevice" is not used in Kaye et al. reference, nevertheless the "product" itself is the main invention of Kaye et al. reference. Particularly, in Figure 2, different shape or form of the photorecognition device with holes on the surface are illustrated. Furthermore, the size or dimension is also within what applicant's recitation, e.g. about 1 to 500 microns. It is therefore a "microdevice".

Applicant argues that the invention of Kaye et al. was to provide method using the device for combinational synthesis, and asserts that examiner misinterpreted the scope and content of the Kaye et al. reference. Applicant asserts that using method of Kaye et al. to study "modulated target molecule", such as "receptor, enzyme or cell", does not involve "separated or isolated; they merely involved in the characterization of the activity or lack

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thereof of a library of compounds” (See page 21, second paragraph and last paragraph).

Applicant asserts that Kay et al. do not disclose or suggest use of its device to manipulate those “modulated” target molecules. Supra.

Applicant arguments have been considered, but are not persuasive.

The reference of Kaye et al. teaches using the microdevice for combinational library screening purpose. Figure 1 of Kay et al. reference provides simplified outline for the combinational library synthesis. Page 19, last two paragraph, Kay et al. also disclose the separation process of the beads (emphasis added). Kay et al. certainly contemplate the subsequent important separation procedure after the screening process. In addition, Kaye et al. also mention that in this separation embodiment, the selected beads with the target molecule thereupon would be placed robotically on the multi-wells and the code on the beads can be read and identified. Surpa. Under such condition, it would be obvious to combine the teachings of secondary Wu et al. reference where the beads are modified with magnetic and with a binding partner thereon to improve the recognition and settling quicker in the multi-wells. Note, Wu et al. reference disclose using magnetic material (attracting by magnetic force) to facilitate the isolation or separation process (See claims 13, 28-31). Thus, the reference of Kaye et al. indeed disclose the manipulation of the target molecule, i.e. separation.

Applicant argues that claim 26, neither Kay et al. nor Wu et al. disclose or suggest the binding partner is a cell, cellular organelle, or virus.

Applicant arguments have been considered, but are not persuasive.

Wu et al. teach that using enzyme, e.g. glucose-6-phosphate dehydrogenase (cellular organelle) as a binding partner for recognition (See Figure 1 and Figure 10 description). Thus, the binding partner disclosed by Wu et al. encompassed both antibody and cellular organelle.

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Applicant argues that claim 12, the material used is aluminum, however Zhou et al. reference is a "large complex arrays addressable micro-electromagnetic units". Applicant argues that the device has no relevance to the instant microdevice.

8. The rejection of 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Kaye et al. in view of Wu et al, and further in view of Zhou et al. (US 6355491) is withdrawn because none of the reference disclose the specific CoTaZr(Cobalt-Tantalum-Zirconium)alloy material for the microdevice. Furthermore, the reference of Zhou et al. is a microarray which dimension exceeds the limitation of instant microdevice, i.e from about 1 to 500 microns.

Allowable Subject Matter

9. Claims 14 and 123-124 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter: no prior art teaches or suggests use of nickel alloy or CoTaZr(Cobalt-Tantalum-Zirconium)alloy for photorecognition microdevice. The closest prior art is the Kaye et al. reference, however Kaye et al. disclose gold, aluminum, silicon dioxide or polyamide or resin (See page 11, line 15-25). No nickel alloy or CoTaZr(Cobalt-Tantalum-Zirconium)alloy material is used or suggested.

Conclusion

11. No claim is allowed.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jacob Cheu

Examiner

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September 13, 2007




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